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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,203	04/13/2004	Que Lan	054030-0056	5029

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EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/823,203

Applicant(s)

LAN ET AL

Examiner

Hope A. Robinson

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8, 10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 10 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. Applicant's response to the Office Action mailed August 23, 2005 on November 22, 2005, is acknowledged.

Claim Disposition

2. Claims 1-7 and 9 have been cancelled. Claim 8 has been amended. Claims 8 and 10-11 are pending and are under examination.

Drawing

3. Previous objection to the drawing is withdrawn based on applicant's arguments presented on page 4 of the Amendment filed November 22, 2005.

New-Specification Objection

4. The specification is objected to because of the following informalities:
On page 27, lines 5-6, the following appears, "Ligand-binding assays were performed to assess whether AeSCP-2 interaction with cholesterol specifically". It is apparent that information is either missing from this sentence or needs to be rearranged.
Correction is required.

Art Unit: 1656

Claim Objection

5. Claim 10 is objected to because of the following informalities:

Claim 10 is objected to for the following typographical error, "gencrated" instead of "generated".

Note that the claim is not amended.

Correction is required.

Withdrawn-Claim Rejections - 35 USC § 112

6. Previous rejections to claims under 35 U.S. C. 112, first paragraph enablement and 112, second paragraph, indefiniteness are withdrawn by virtue of submission of an amendment.

New-Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 8 and 10-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention. The specification does not contain the required information for a deposit (see page 27). Use of the claimed invention requires deposited material, but deposit of material does not

ensure that it will readily be available during the duration of the patent. Applicant's deposit would satisfy the enablement requirements of 35 U.S.C. 112, provided that the following conditions are met. It is noted that the specification on page 27 indicates that a deposit was made into NCBI EST databank (BQ785056.1) on July 26, 2002 and that the clone Ae4-339 is the first found in insects, however, no information regarding public availability is provided or if the deposit was made under the Budapest Treaty. No information is provided as to whether the clone was deposited at a Repository, the date of the deposit and the name/address of said Repository. Thus, the invention is not adequately described and one skilled in the art would not have access to the necessary materials to be able to practice the claimed invention. Applicant makes reference to the NCBI deposit number, however, this is not sufficient to illustrate that the information is publicly available or give the assurance that all of the conditions of 37 CFR 1.801-1.809 have been met. If deposits have not been made under the Budapest Treaty, then in order to certify that the deposits meet the criteria set forth in 37 CFR 1.801-1.809, applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (A) During the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (B) All restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (C) The deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (D) The deposits were viable at the time of deposit;

Art Unit: 1656

(E) The deposits will be replaced if they should ever become non-viable.

This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each member State. Amendment of the specification to disclose the date of the deposit and the complete name and address of the depository is required. For further information concerning deposit practice, applicants attention is directed to In re Lundark 773 F 2d 1216 227 USPQ CCAFC and 37 CFR 1.801-1.809.

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

8. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention.

The claimed invention is directed to a method for identifying whether a compound is binds or interacts with AeSCP-2 and the claim is described solely by function, not a structure. Therefore, the skilled artisan cannot envision the detailed chemical structure of the claimed protein thus, the claimed invention lacks adequate written description. It is noted that claim 11 which depends from claim 10 recite the structure, "SEQ ID NO:3", however, independent claim 10 needs to stand on its own. Thus the claim lack adequate written description to demonstrate to a skilled artisan that applicant was in possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations

Art Unit: 1656

using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. See *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.1997). Therefore, a biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. For example, even though a genetic code table would correlate a known amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of a naturally occurring mRNA or its corresponding cDNA. See *MPEP 2163*.

Further, *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991), states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of encoded proteins, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993). See *MPEP 2163*.

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Response to Arguments

9. The response filed on November 22, 2005 has been considered. Note that the rejections of record have been withdrawn based on amendments made to the claims or arguments presented. However, a new ground of rejection has been instituted under 35 U.S.C. 112, first for the reasons stated above. In addition new objections have been made to the specification and claims.

Conclusion

10. No claims presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1656

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS ~~AA~~
Patent Examiner 2/13/06

HOPE ROBINSON
PATENT EXAMINER